UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,877	02/20/2004	Gary A. Howard	7172USO1	7736

41155 7590 06/18/2010

BRIAN R. WOODWORTH
275 N. FIELD DRIVE
DEPT. NLEG BLDG H-1
LAKE FOREST, IL 60045-2579

EXAMINER	
GILLIGAN, CHRISTOPHER L	
ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
06/18/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,877	HOWARD ET AL.	
	Examiner	Art Unit	
	LUKE GILLIGAN	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-241* is/are pending in the application.

4a) Of the above claim(s) *1-156 and 219-240* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *157-218 and 241* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/11/05, 4/29/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Applicant's election without traverse of claims 157-218 and 241 in the reply filed on 5/12/10 is acknowledged.

2. Claim 1-156 and 219-240 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/12/10.

Claim Objections

3. Claim 162 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The additional limitation recited in claim 162 is already recited in claim 157, from which claim 162 depends.

4. Claim 207 is objected to because of the following informalities: There are two claims numbered 207. Appropriate correction is required.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 241 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

7. Claim 241 is directed to a "computer readable medium storing a program…" Applicant's specification does not provide a definition of "computer readable medium." Therefore, given the broadest reasonable interpretation, a computer readable medium can encompass transitory media such as carrier waves and signals transmitted over a network. Such transitory media are non-statutory subject matter. Therefore, claim 241 is directed to non-statutory subject matter.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 180-183, 185, 186, 189, 190, 193-203, 205-207 (both 207s), and 193-199 are rejected under 35 U.S.C. 102(b) as being anticipated by Ford, US Patent No. 5,681,285.

10. As per claim 180, Ford teaches a method of configuring a drug library for use by a medication administering device, the method comprising: providing a host computer (see column 10, lines 64-67); providing a user customizable worksheet of medical device parameters (see column 11, lines 22-28); configuring the worksheet by entering data into the worksheet (see column 11, lines 22-29); validating the entered data in real time (see column 19, lines 7-32); and downloading the worksheet to one or more medication administering devices (see column 11, lines 33-38).

11. As per claim 181, Ford teaches the method of claim 180 as described above. Ford further teaches the customizable worksheet is selected from a plurality of worksheets (see column 11, lines 28-29; i.e. separate files).

12. As per claim 182, Ford teaches the method of claim 180 as described above. Ford further teaches the medical device parameters include a drug library (see column 11, lines 22-28).

13. As per claim 183, Ford teaches the method of claim 180 as described above. Ford further teaches the worksheet can be configured based on a selected clinical care area (see column 13, lines 30-33).

15. As per claim 185, Ford teaches the method of claim 180 as described above. Ford further teaches data is validated using constraint objects, which define an implementation for validating data inputs (see column 19, lines 7-32).

16. As per claim 186, Ford teaches the method of claim 180 as described above. Ford further teaches a drug library is exported from the host computer to a second computer (see column 10, lines 64-67).

17. As per claim 189, Ford teaches the method of claim 180 as described above. Ford further teaches displaying at least a portion of the worksheet during the configuration of the worksheet (see paragraph 12, lines 41-42).

18. As per claim 190, Ford teaches the method of claim 189 as described above. Ford further teaches displaying a reference worksheet on the same screen as the worksheet under configuration (see column 12, lines 1-4).

19. As per claim 193, Ford teaches the method of claim 180 as described above. Ford further teaches configuring the worksheet includes defining a set of rules governing individual drugs in the drug library (see column 12, lines 18-29).

20. As per claim 194, Ford teaches the method of claim 193 as described above. Ford further teaches the set of rules include rules relating to drug concentrations and dosages (see column 12, lines 11-19).

21. As per claim 195, Ford teaches the method of claim 193 as described above. Ford further teaches the set of rules include rules that define drug delivery limits (see column 12, lines 11-21).

22. As per claim 196, Ford teaches the method of claim 193 as described above. Ford further teaches the set of rules include medication administering device level rules (see column 12, lines 22-29).

23. As per claim 197, Ford teaches the method of claim 196 as described above. Ford further teaches the device level rules relate to capabilities or limitations of certain medication administering devices (see column 12, lines 22-29).

24. As per claim 198, Ford teaches the method of claim 193 as described above. Ford further teaches the set of rules include clinical care area level rules, specific to certain clinical care areas (see column 13, lines 30-33).

25. As per claim 199, Ford teaches the method of claim 193 as described above. Ford further teaches the set of rules include patient level rules, specific to certain patients (see column 18, lines 5-8).

26. Claims 200-203, 205-207 (both 207s), and 193-199 recite substantially similar limitations to those already addressed in claims 180-183, 185-186, 189-190, and 193-199 and, as such, are rejected for similar reasons as given above.

Claim Rejections - 35 USC § 103

27. he following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

28. Claims 157-166, 168-170, 173-179, 184, 188, 204, 209, and 241 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ford, US Patent No. 5,681,285 in view of Staehr, US Patent No. 7,256,888

29. As per claim 184, Ford teaches the method of claim 180 as described above. While Ford teaches setting limits (see column 12, lines 18-24), Ford does not explicitly teaches setting hard and soft limits. Staehr teaches setting hard and soft limits for a drug library (see column 13, lines 19-21). It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature to the system of Ford because the individual elements were old and well known, the combination would not have required further modification to the system of Ford, and the results of the combination would have been predictable.

30. As per claim 188, Ford teaches the method of claim 180 as described above. Ford does not explicitly teach importing the drug library to the host computer from a

second computer. Staehr teaches a system for managing patient and drug information including transferring data from a second computer to a host computer (see column 6, lines 52-59). It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature to the system of Ford because the individual elements were old and well known, the combination would not have required further modification to the system of Ford, and the results of the combination would have been predictable.

31. Claims 157-166, 168-170, and 173-179 recite substantially similar limitations to those already addressed in claims 180-186, 188-190, and 193-199 and as such, are rejected for similar reasons as given above.

32. Claims 204 and 209 recite substantially similar additional limitations to those already addressed in claims 184 and 188 and, as such, are rejected for similar reasons as given above.

33. Claim 241 recites substantially similar computer readable medium limitations to method claims 180 and 184 and, as such, is rejected for similar reasons as given above.

34. Claims 167, 187, and 208 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ford, US Patent No. 5,681,285 in view of Official Notice.

35. As per claim 187, Ford teaches the method of claim 186 as described above. Ford does not explicitly teach the drug library is exported using a binary format. However, the examiner takes Official Notice that binary format for transferring data in a digital computer environment is old and well known in the art. Therefore, it would have

been obvious to one of ordinary skill in the art at the time of the invention to add this feature to the system of Ford because the individual elements were old and well known, the combination would not have required further modification to the system of Ford, and the results of the combination would have been predictable.

36. Claims 167 and 208 recite substantially similar additional limitations to those already addressed in claim 187 and, as such, are rejected for similar reasons as given above.

37. Claims 171, 172, 191, 192, 210, and 211 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ford, US Patent No. 5,681,285 in view of Steen, US Patent No. 7,636,718.

38. As per claim 191, Ford teaches the method of claim 180 as described above. Ford does not explicitly teach editing a drug formulary. Steen teaches editing a drug formulary (see column 6, lines 37-39). It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature to the system of Ford because the individual elements were old and well known, the combination would not have required further modification to the system of Ford, and the results of the combination would have been predictable.

39. As per claim 192, Ford in view of Steen teaches the method of claim 191 as described above. Ford further teaches providing a split screen display for configuring the worksheet (see column 12, lines 1-10). However, as described above, Ford does not explicitly teach editing a drug formulary. Steen teaches editing a drug formulary

(see column 6, lines 37-39). It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature to the system of Ford because the individual elements were old and well known, the combination would not have required further modification to the system of Ford, and the results of the combination would have been predictable.

40. Claims 171, 172, 210, and 211 recite substantially similar additional limitations to those already addressed in claims 191 and 192 and, as such, are rejected for similar reasons as given above.

Conclusion

41. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUKE GILLIGAN whose telephone number is (571)272-6770. The examiner can normally be reached on Monday-Thursday and every other Friday.

42. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on 571-272-6787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

43. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. Luke Gilligan/
Primary Examiner, Art Unit 3626